FEB 2 8 2001

K010444

7.0 510(k) Summary of Safety and Effectiveness for Advantage™ Single-Use Electrosurgical Attachment

A. Submitter Information

Submitter's Name:	Davol, Inc. Subsidiary of C. R. Bard, Inc.
Address:	100 Sockanossett Crossroad Cranston, RI 02920
Telephone:	401-463-7000 ext. 2529
Fax:	401-463-3845
Contact Person:	Ruth C. Forstadt
Date of Preparation:	January 19, 2001

B. Device Name

Trade name:	Advantage™ Single-Use Electrosurgical Attachment
Common/Usual Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories

C. Predicate Device Name

Disposable Unipolar Coagulator Probe System (Davol) – K921716/B
ConMed® Universal Plus® Electrosurgical Blade – K991855

D. Device Description

Advantage™ Single-Use Electrosurgical Attachment consists of a distal partially insulated metal tip attached to a metal tube connected at the proximal end to the probe base. The probe base has fins for easy one-handed rotation and orientation of the tip. An extendible sheath encloses the metal tube. The unipolar high frequency cord is attached to the vertical multilam plug. The proposed device can be used with the Nezhat-Dorsey® Trumpet Valve, Nezhat-Dorsey® SmokEvac® Trumpet Valve and Davol® Trumpet Valves. The device is 5mm/33cm in length with the following electrode tip configurations: Corbitt Spatula tip, J-Hook tip, L-Hook tip, Ball tip and Needle tip. The Advantage™ Single-Use Electrosurgical Attachment will be supplied sterile.

E. Intended Use

Advantage™ Single-Use Electrosurgical Attachments are intended for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures (e.g. laparoscopic cholecystectomy, appendectomy and herniorrhaphy). They are not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tube.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use.

Advantage™ Single-Use Electrosurgical Attachment has similar indications for use as the predicate devices in that they are indicated for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures. Components of the proposed device are made from materials and design similar to the predicate devices, and all materials are biocompatible.

The proposed device has the same technological characteristics and fundamental scientific technology as the current disposable electrosurgical attachment. These include a sheath to protect the patient from possible tip harm while orientating, and a quick-disconnect base for easy attachment to the trumpet valve. Differences between the proposed device and the current device include a stiffer sheath, the addition of the "star wheel" fin design probe base, two new tip shape configurations (ball and needle tips), the addition of the stick resistant tip coating, and the change in tip welding location on the tube.

Similarities between the proposed device and the predicate ConMed® Universal Plus® Laparoscopic Electrosurgical Blade device include a sheath to protect the patient from possible tip harm while orientating, a variety of tip configurations, a stick resistant tip coating, and an unoccluded tip inner diameter. Differences between the proposed device and the ConMed® Universal Plus® Laparoscopic Electrosurgical Blade include the material of the stick resistant tip coating, and the length of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2001

Davol, Inc.
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

Re: K010444
Trade Name: Advantage™ Single-Use Electrosurgical Attachment
Regulatory Class: II
Product Code: GEI
Dated: February 13, 2001
Received: February 14, 2001

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010444

Device Name: Advantage™ Single-Use Electrosurgical Attachments

Indications for Use:

These instruments are intended for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures (e.g. laparoscopic cholecystectomy, appendectomy and herniorrhaphy). They are not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tube.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010444

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)